DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2015

EngagementHealth, LLC
c/o Jorge Millan, Ph.D.
Hialeah Technology Center
601 West 20 St.
Hialeah, FL 33010

Re: K140360
Trade/Device Names: EngagementHealth Kiosk
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: February 25, 2015
Received: March 2, 2015

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

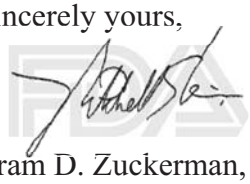
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

EngagementHealth Kiosk

Indications for Use:

The EngagementHealth Kiosk is intended to be used by the general public as a non-invasive multi-functional unit which measures a person's weight, blood pressure and heart rate. The kiosk is not intended to be a diagnostic device and does not perform any diagnoses. Rather, the kiosk provides the user with weight and systolic/diastolic blood pressure to be used as supplemental data when consulting a professional physician. The EngagementHealth Kiosk is intended to be fully unattended and placed within public or corporate environments. The user can choose to send the data to the EngagementHealth web portal for later data visualization.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: __K140360_____

Submitter

224 North Des Plaines Street
Suite 401
Chicago, IL 60661
Registration #: To be applied for

Official correspondent :

Jorge Millan, PhD
Email: jmillan@hiatec.org
601 West 20 St
Hialeah, FL 33010
Phone : (305) 925-1260

Date Prepared:

February 27, 2015

Device name and classification:

- Device Name: EngagementHealth Kiosk
- Common Name: Kiosk for Measurement of Health Parameters
- Classification Name: System, measurement, noninvasive blood pressure.
- Classification Number: 870.1130
- Product Code: DXN
- Classification: Class II

Predicate Devices:

- **PharmaSmart Inc. – PharmaSmart PS1000/PS1500/PS2000 Public Use Blood Pressure Monitor (K063137)**
- **Stayhealthy Kiosk SH650-C (K123539)**
- **A & D Medical – TM-2655 Digital Blood Pressure Monitor (K010828)**

Device Description:

The EngagementHealth Kiosk is a device which provides a method for identifying a person's systolic and diastolic blood pressure, pulse rate, weight and displays the results onto the touch screen LCD computer screen. The individual using the device is seated during the entire operation of the device for accurate blood pressure readings.

Indications for Use:

The EngagementHealth Kiosk is intended to be used by the general public as a non-invasive multi-functional unit which measures a person's weight, blood pressure and heart rate. The kiosk is not intended to be a diagnostic device and does not perform any diagnoses. Rather, the kiosk provides the user with weight and systolic/diastolic blood pressure to be used as supplemental data when consulting a professional physician. The EngagementHealth Kiosk is intended to be fully unattended and placed within public or corporate environments. The user can choose to send the data to the EngagementHealth web portal for later data visualization.

Effectiveness and Safety Contraindications:

Clinical Test

Clinical testing is not required

Non-clinical test:

The EngagementHealth Kiosk has been tested and found to be in compliance with recognized safety standards.

The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Comparison to the predicate device:

The subject device has similar technology characteristics and intended use as predicate devices legally marketed in the US.

Substantially Equivalent Determination:

EngagementHealth Kiosk is substantially equivalent in technological characteristics and intended use to legally marketed devices compared herein. Further, the EngagementHealth health kiosk is as safe, as effective and performs as well as the predicate devices.